HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1283B

MAR 25 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

REGISTERED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. David R. Malys
President
Ferraris Medical, Inc.
P.O. Box 344
9681 Wagner Road
Holland, New York 14080

Re: Pocketpeak Peak
Flow Meter

Dear Mr. Malys:

The Food and Drug Administration (FDA) has reviewed labeling and promotional materials for the "Pocketpeak, Peak Flow Meter," dated 1994. This product is manufactured by Ferraris Medical, Inc., Holland, New York and is a device as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Pocketpeak Peak Flow Meter is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) or an approved application for an investigational device exemption (IDE) under section 520(g).

The PocketPeak Peak Flow Meter is misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the new intended use(s) of the device was not provided to FDA as required by Section 510(k), and the device was not found to be substantially equivalent to a predicate device.

The phrases "alerts you three days in advance that you are headed for an asthma crisis," "may actually help you prevent asthma attacks," and similar language in the video "Peak Flow Monitoring," and in the brochure "Pocketpeak, Peak Flow Meter, Operating & Cleaning Instructions Patient Diary," clearly make claims for new intended uses for your device. This device has not received clearance for the intended use(s) of controlling asthma, preventing asthma flare-ups, or improving clinical results. These claims for new intended uses elevate your device to Class III.

Also, the Ferraris device, cleared in 1993, as shown in the draft product literature, is a prescription device, in accordance with the current review practice of regarding all devices with zone labels as prescription devices. The marketed device and labeling have no prescription labeling.

The device reviewed, a "universal range" (50-720 lpm), does not correspond to the device reviewed as K924343. K924343 is for devices with a range of 80 to 780 (adult) or 50 to 400 (pediatric). Have you submitted a 510(k) for the current "universal range" device?

Further, the tape reviewed alludes to use of the device among several patients, while the device reviewed in K924343 is for single patient use. What changes have been made in the device labeling/sterilization to address this new use?

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter also may be reflected in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing all materials to assure compliance with applicable regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should also include steps being taken to address any misleading information currently in the market place and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the following individual:

James W. Eisele (HFZ-343)
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
2098 Gaither Road
Rockville, MD 20850

Sincerely yours,

Larry D. Spears for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health